

SUPPORT FOR THE AMENDMENTS

Claims 6-10 have been canceled.

Claims 1 and 2 have been amended.

Claims 15 and 16 have been added.

The amendment of Claim 2 is supported by the corresponding claims as previously presented. The amendment of Claim 1 and new Claims 15 and 16 are supported by the specification at, for example, page 5, lines 23-25.

No new matter has been added by the present amendment.

REMARKS

Claims 1-5 and 11-16 are pending in the present application.

The rejections of: (a) Claims 1, 3, 4, and 13 under 35 U.S.C. §102(b) over Chen et al (US 6,383,471), and (b) Claims 2, 5, 11, 12, and 14 under 35 U.S.C. §103(a) over Chen et al (US 6,383,471) in view of Moskowitz (US 5,767,177), are obviated in part by amendment and traversed in part.

Chen et al disclose a composition containing, as it appears, any and every conceivable hydrophobic therapeutic agent and a carrier, where the carrier includes a surfactant and an ionizing agent capable of ionizing the ionizable hydrophobic therapeutic agent. However, at no point do Chen et al disclose or suggest a pharmaceutical composition for nasal administration as presently claimed. Specifically, at no point do Chen et al disclose or suggest a pharmaceutical composition that is in liquid form and under pressure in a pressurized container or is contained in a non-pressurized container and said composition is such that it is released in the form of an aerosol or spray during nasal administration where the pharmaceutical composition contains zolpidem, a pharmaceutically acceptable salt thereof, or a combination thereof, and a pharmaceutically acceptable nasal carrier. Therefore, Chen et al do not anticipate the claimed invention.

Moskowitz is cited by the Examiner to allegedly compensate for noted deficiencies in Chen et al with respect to failing to specifically teach a solution of a 2:1 zolpidem/tartrate salt in sterile purified water (Claim 2), the amounts of zolpidem disclosed in Claims 5, 11, and 12, or the pH of 3 to 10 (Claim 14). Applicants make no statement with respect to the propriety of this allegation and in no way acquiesce to the same. However, Applicants

submit that Moskowitz fails to compensate for the aforementioned deficiencies in Chen et al (i.e., failing to disclose the specifically claimed composition). Accordingly, the claimed invention is not obvious in view of the combined disclosures of Chen et al and Moskowitz.

Applicants request withdrawal of these grounds of rejection.

The rejection of Claim 1 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

The Examiner alleges that the “specific prodrugs of zolpidem are not described in the specification” and, as such, the term “prodrug” is indefinite. Applicants make no statement with respect to the propriety of this allegation and in no way acquiesce to the same. For the sole purpose of expediting examination, Applicants have removed the “prodrug” language from Claim 1.

Withdrawal of this ground of rejection is requested.

The informalities objection to Claim 2 is obviated by amendment. Applicants have amended Claim 2 as suggested by the Examiner. As such, withdrawal of this ground of objection is requested.


Application Serial No. 10/801,856
Response to Office Action mailed March 14, 2008

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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